REMARKS

I. Status of the Claims

Claims 1-5, 14-18 and 20-34 are currently pending in the application, with claims 1, 20 and 26 being the independent claims. Claims 10-13 are canceled without prejudice to or disclaimer of the subject matter therein. Claims 6-9 and 19 were previously canceled. Claims 20-31 are withdrawn from consideration pursuant a restriction requirement. Thus, claims 1-5, 14-18 and 32-34 are under examination.

II. The Amendments to the Claims

Claims 1-5 and 14 are amended. Claim 1 is amended to recite a single biological sample storage device for storing and testing blood or blood products, comprising a container for receiving and storing blood or blood products on day 1 and six outlets for subsequent testing of the blood or blood products, and specify that each of the outlets comprises at least a first section for holding a portion of the blood or blood products, a second section comprising a lysis buffer or an isotonic buffer, and a third section comprising at least two test reagents, wherein each of the outlets is arranged as a protruding element from the container, and wherein at least one of the two reagents is bound to a solid support or is lyophilized. Support for the amendments to claim 1 may be found, *inter alia*, at pages 8-9 of the original specification, Figure 1 and claims 1-5 and 10-18 as previously presented.

Claim 2 is amended to recite that the first section in each outlet is in open connection to the container. Support for the amendment to claim 2 may be found, *inter alia*, in paragraph [0024] at page 8 of the original specification, Figure 1 and claims 1-5 and 10-18 as previously presented.

Claim 3 is amended to recite that the first section in each outlet is permanently sealed off from the container immediately prior to testing. Support for the amendment to claim 3 may be found, *inter alia*, in paragraph [0024] at page 8 of the original specification, Figure 1 and claims 1-5 and 10-18 as previously presented.

Claim 4 is amended to recite that the second section in each outlet is sealed off from the first section via a pressure sensitive seal, and applied pressure causes the seal to break and

the blood or blood product to mix with the lysis buffer or the isotonic buffer. Support for the amendment to claim 4 may be found, *inter alia*, in paragraph [0024] at page 8 of the original specification, Figure 1 and claims 1-5 and 10-18 as previously presented.

Claim 5 is amended to recite that the third section in each outlet is sealed off from the second section via a pressure sensitive seal, and applied pressure causes the seal to break and the test reagents to mix with the lysed blood or blood product. Support for the amendment to claim 5 may be found, *inter alia*, in paragraph [0024] at pages 8-9 of the original specification, Figure 1 and claims 1-5 and 10-18 as previously presented.

Claim 14 is amended to correct dependency.

These amendments do not introduce any new matter into the application and their entry is respectfully requested.

III. The Rejection Under 35 U.S.C. § 102(b)

The Office Action, at pages 3-6, rejects claims 1-5, 10-14, 17 and 32-34 under 35 U.S.C. § 102(b) as allegedly being anticipated by WO 99/26724 to Muir *et al.* ("Muir"). According to the Office Action, Muir discloses a device comprising a fluid sample collection unit attached to a reaction chamber. Applicants respectfully traverse this ground of rejections.

A. Summary of the Claimed Invention

Claim 1, as amended, recites a *single* biological sample storage device for storing and testing blood or blood products, comprising a container for receiving and storing blood or blood products *on day 1*; and *six outlets* for *subsequent* testing of the blood or blood products, and specifies that *each of the outlets comprises at least a first section for holding a portion of the blood or blood products, a second section comprising a lysis buffer or an isotonic buffer, and a third section comprising at least two test reagents*, wherein *each of the outlets is arranged as a protruding element from the container*, and wherein at least one of the two reagents is bound to a solid support or is lyophilized.

B. The Cited Reference Fails to Teach Each and Every Element of the Claimed Invention

Muir discloses a device comprising a receptable housing a reaction chamber comprising one compartment containing one reagent (*see* pages 3-4). Muir fails to disclose a *single* device comprising a container for receiving and storing blood or blood products on day 1; and *six outlets* for subsequent testing of the blood or blood products, wherein *each of the outlets comprises at least a first section for holding a portion of the blood or blood products, a second section comprising a lysis buffer or an isotonic buffer, and a third section comprising at least two test reagents*, and wherein each of the outlets is arranged as a protruding element from the container, and at least one of the two reagents is bound to a solid support or is lyophilized. In fact, the device disclosed by Muir does not have a multiple outlet structure that allows testing of blood or blood products at subsequent times. Thus, Muir fails to anticipate the claimed invention.

Reconsideration and withdrawal of this ground of rejection are therefore respectfully requested.

IV. <u>The Rejections Under 35 U.S.C. § 103</u>

1. The Rejection of Claims 14-17

The Office Action, at pages 7-10, rejects claims 14-17 under 35 U.S.C. § 103(a) as allegedly being unpatentable over WO 99/26724 to Muir *et al.* ("Muir") in view of U.S. Patent No. 5,589,332 B1 to Shih *et al.* ("Shih") Applicants respectfully traverse this ground of rejection.

The Supreme Court recently reaffirmed the Graham factors for determining obviousness in *KSR Int'l Co. v. Teleflex Inc.* (No. 04-1350) (U.S., April 30, 2007). The Graham factors, as outlined by the Supreme Court in *Graham et al. v. John Deere Co. of Kansas City et al.*, 383 U.S. 1 (1966), are: 1) determining the scope and contents of the prior art; 2) ascertaining the differences between the claimed invention and the prior art; 3) resolving the level of ordinary skill in the pertinent art; and 4) evaluating evidence of secondary consideration. The Supreme Court recognized that a showing of "teaching, suggestion, or motivation" to combine the prior art to meet the claimed subject matter could

provide a helpful insight in determining whether the claimed subject matter is obvious under 35 U.S.C. § 103(a), and held that the proper inquiry for determining obviousness is whether the improvement is more than the predictable use of prior art elements according to their established functions. The Court noted that it is "*important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the [prior art] elements" in the manner claimed*, and specifically stated:

> Often, it will be necessary . . . to look to interrelated teachings of multiple patents; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was ***an apparent reason to combine the known elements in the fashion claimed*** by the patent at issue. To facilitate review, this analysis should be made explicit.

KSR Int'l Co. v. Teleflex Inc., slip op. at 14 (emphasis added).

A. The Cited References Fail to Teach Each and Every Element of the Claimed Invention

The inability of Muir to teach or suggest the invention of claims 1-5, 10-14, 17 and 32-34 is demonstrated above. The additional reference, Shih, does not remedy the deficiencies of Muir.

Although Shih discloses the use of a ribozyme as a diagnostic tool to detect the presence a nucleic acid in a solution, the reference fails to teach or suggest a device for storing and testing blood or blood products as claimed in the present application. Thus, Shih, like Muir, fail to disclose or suggest the claimed invention.

B. There is no Reason to Combine the known Elements in the Fashion Claimed

The Office Action contends that one of ordinary skill in the art would have been motivated to combine the teachings of Muir with the teachings of Shih to detect the presence of nucleic acids in a sample, and alleges that "it would have been obvious to one of ordinary skill in the art at the time the invention was made to include the diagnostic ribozymes and RNA co-targets of Shih in the blood storage and testing device of Muir because both Muir and Shih teach testing of blood for pathogens".

This allegation, however, is not supported by the disclosure of the prior art. As stated above, Muir fails to teach or suggest a device having a multiple outlet structure that allows testing of blood or blood products at subsequent times. Further, Shih teaches that the ribozyme reactions can be carried out in standard reaction vessels for assays, such as microtiter plates (*see* col. 6, lines 4-11 and col. 7, lines 40-50). Accordingly, one of ordinary skill in the art would not have been motivated to modify the device disclosed by Muir to include the ribozyme system disclosed by Shih, because Shih fails to teach or suggest that the ribozyme system could be applied to a device for storing and testing blood or blood products as claimed in the present application. Thus, the Office Action's alleged reason to combine the teachings of the prior art is impermissible.

For at least these reasons, the rejection of claims 14-17 under 35 U.S.C. § 103(a) is improper. Reconsideration and withdrawal of this ground of rejection are therefore respectfully requested.

2. The Rejection of Claim 18

The Office Action, at pages 10-11, rejects claim 18 under 35 U.S.C. § 103(a) as allegedly being unpatentable over WO 99/26724 to Muir *et al.* ("Muir") and U.S. Patent No. 5,589,332 B1 to Shih *et al.* ("Shih"), as applied to claims 14-17, and further in view of U.S. Patent No. 6,251,599 B1 to Chen *et al.* ("Chen"). Applicants respectfully traverse this ground of rejection.

The inability of Muir and Shih to teach or suggest the invention of claims 1-5, 10-17 and 32-34 is demonstrated above. The additional reference, Chen, does not remedy the deficiencies of Muir and Shih. Rather, Chen is directed to compositions comprising a nucleic acid condensed with a polycation that are stable when subjected to destabilizing conditions, such as lyophilizing, freeze-twawing and prolonged liquid storage. The reference fails to teach or suggest a device for storing and testing blood or blood products as claimed in the present application. Thus, Chen, like Muir and Shih, fail to disclose or suggest the claimed invention. Therefore, the rejection is improper.

Reconsideration and withdrawal of this ground of rejection are respectfully requested.

V. Other Matter

The Office Action, at page 8, seems to imply that a complex of a ribozyme and targeting molecule as claimed in claim 15 of the present application would be inactive, "*because Shih teaches [that] an activated ribozyme requires a ribozyme, a co-targeting molecule and a target molecule*". The Office Action's allegation, however, is not supported by the disclosure of Shih. In fact, Shih discloses a bimolecular system where an active ribozyme is formed by the complex of ribozyme molecule and disease target molecule, with the cleavage site located in the ribozyme molecule, in the absence of a co-target molecule (*see* col. 4, lines 62-67). Thus, the presence of a co-target molecule is not required in a ribozyme system. Therefore, claim 15 is fully enabled.

CONCLUSION

All of the stated grounds of objections and rejections have been properly traversed or rendered moot. Therefore, the present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check or credit card payment form being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicants hereby petition for such extension under 37 C.F.R. § 1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

Date January 22, 2008

By _____
Richard C. Peet
Attorney for Applicants
Registration No. 35,792

FOLEY & LARDNER LLP
Customer Number: 22428
Telephone: (202) 672-5483
Facsimile: (202) 672-5399